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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,012	04/13/2004	Micheal Patrick Dillon	R0130D-CON	4690

24372 7590 02/12/2007
ROCHE PALO ALTO LLC
PATENT LAW DEPT. M/S A2-250
3431 HILLVIEW AVENUE
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/823,012	Applicant(s) DILLON ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48 and 51-62 is/are pending in the application.
- 4a) Of the above claim(s) 53 and 55-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48, 51, 52 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/11/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

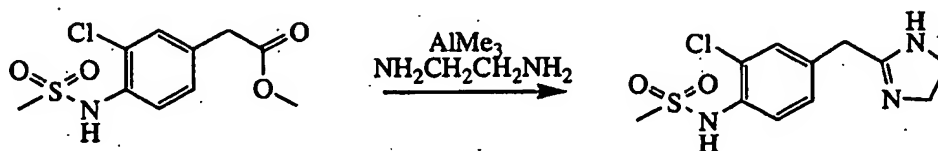
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DETAILED ACTION

Claims 48 and 51-62 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I, and the species of Example 3 in step 4 on page 49 (reproduced below), in the reply filed on December 16, 2004 was acknowledged in a previous Office Action.

Step 4

The requirement was deemed proper and made FINAL in a previous Office Action.

Claims 53 and 55-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being

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drawn to nonelected inventions. Election was made **without** traverse in the reply filed on December 16, 2004.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on December 11, 2006.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these objections will not be addressed.

Terminal Disclaimer

The terminal disclaimer filed on May 10, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the

expiration date of U.S. Patent 6,756,395 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The Declaration under 37 CFR 1.132 filed May 10, 2006 by Counde O-Yang has been re-assessed since Applicant has provided further explanation of the showing; has submitted expanded forms of Figure 1 and Figure 2; and has amended the claims.

Response to Amendment

The Declaration under 37 CFR 1.132 filed May 10, 2006 by Counde O-Yang is insufficient to overcome the rejection of claims 48, 51, 52 and 54 based upon 35 USC 103 as set forth in the last Office action because the showing is not commensurate in scope with the currently amended claims. In re Greenfield, 197 U.S.P.Q. 227 (1978) and In re Lindner, 173 U.S.P.Q. 356 (1972). Also see M.P.E.P. 716.02(d).

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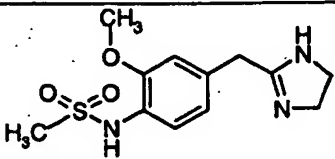
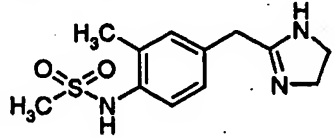
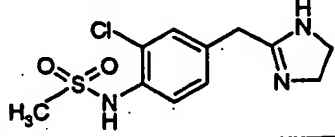
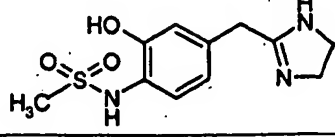
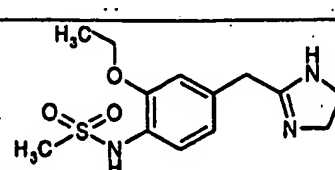
Applicant's showing is not commensurate in scope because Applicant has only compared one of the compounds of the instant claimed invention with only one compound of Cournoyer et al. The comparison of only one compound is insufficient to show a true trend that the *para* compounds have unexpected and beneficial properties over the *meta* compounds. By comparing the compounds found in Table 1 of the instant specification starting at page 19 (reproduced below) with the compounds of Cournoyer et al. (relevant columns reproduced below), the following table illustrates some of the other compounds which should also have been compared to persuasively show that the instant claimed compounds have unexpected, beneficial and unobvious results over the compounds of Cournoyer et al. in treating urinary incontinence while not increasing blood pressure. See, for example, the table below.

Applicants' Compounds	Cournoyer et al. Compounds
Compound 2 -----▶	The Compound in column 40, lines 10-12

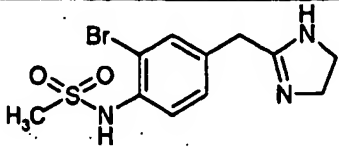
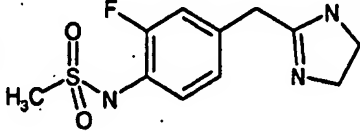
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Compound 3 -----▶	The Compound in column 39, lines 16-18
Compound 4 -----▶	The Compound in column 39, lines 38-40
Compound 5 -----▶	The Compound in column 39, lines 32-34
Compound 29 -----▶	
Compound 40 -----▶	The Compound in column 39, lines 46-48

Instant Compounds found on pages 19 and 21-24,
 respectively, of the instant specification that are
 embraced by independent claim 48 follow.

2	<i>N</i> -[4-(4,5-Dihydro-1 <i>H</i> -imidazol-2-ylmethyl)-2-methoxy-phenyl]-methanesulfonamide;	2	
3	<i>N</i> -[4-(4,5-Dihydro-1 <i>H</i> -imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide	2	
4	<i>N</i> -[2-Chloro-4-(4,5-dihydro-1 <i>H</i> -imidazol-2-ylmethyl)-phenyl]-methanesulfonamide	3	
5	<i>N</i> -[4-(4,5-Dihydro-1 <i>H</i> -imidazol-2-ylmethyl)-2-hydroxy-phenyl]-methanesulfonamide	2	
29	<i>N</i> -[2-Ethoxy-4-(4,5-dihydro-1 <i>H</i> -imidazol-2-ylmethyl)-phenyl]-methanesulfonamide	4	

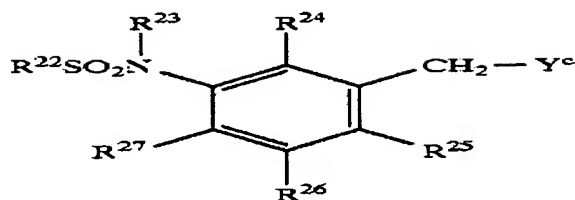
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33	<i>N</i> -[2-Bromo-4-(4,5-dihydro-1 <i>H</i> -imidazol-2-ylmethyl)-phenyl]-methanesulfonamide	4	
40	<i>N</i> -[4-(4,5-Dihydro-1 <i>H</i> -imidazol-2-ylmethyl)-2-fluoro-phenyl]-methanesulfonamide	4	

Compounds of Cournoyer et al. found in Columns 39 and 40.

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wherein Y^c is 2-imidazoline, and

R^{22}	R^{23}	R^{24}	R^{25}	R^{26}	R^{27}	
CH_3	H	CH_3	H	H	H	15
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)						
CH_3	H	H	H	H	CH_3	20
(N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)						
CH_3	H	H	H	Cl	CH_3	
N-[3-chloro-5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide						
CH_3	H	H	H	Br	CH_3	25
(N-[3-bromo-5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)						
CH_3	H	H	H	H	OCH_3	
(N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methoxy-phenyl]-methanesulfonamide)						
CH_3	H	H	H	H	H	30
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-phenyl]-methanesulfonamide)						
CH_3	H	H	H	H	OH	
(N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-hydroxy-phenyl]-methanesulfonamide)						
CH_3	H	H	F	H	H	35
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-4-fluoro-phenyl]-methanesulfonamide)						
CH_3	CH_3	CH_3	H	H	H	
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-N-methyl-methanesulfonamide)						
CH_3	H	Cl	H	H	H	40
(N-[2-chloro-3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-phenyl]-methanesulfonamide)						
CH_3	H	C_6H_5	H	H	H	
(N-[6-(4,5-dihydro-1H-imidazol-2-ylmethyl)-biphenyl-2-yl]-methanesulfonamide)						
CH_3	H	CH_3	CH_3	H	H	45
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2,4-dimethyl-phenyl]-methanesulfonamide)						
CH_3	H	H	H	H	F	
(N-[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-fluoro-phenyl]-methanesulfonamide)						
CH_3	H	CH_3	H	H	CH_3	50
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2,6-dimethyl-phenyl]-methanesulfonamide)						
CH_3	H	CH_3	H	CH_3	H	
(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2,6-dimethyl-phenyl]-methanesulfonamide)						
CH_3	H	$CH=CH_2$	H	H	H	55
(N-[3-(3H-imidazol-4-ylmethyl)-2-methyl-phenyl]-methanesulfonamide)						
CH_3	H	C_6H_4	H	H	H	

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-continued

	R ²²	R ²³	R ²⁴	R ²⁵	R ²⁶	R ²⁷
	methanesulfonamid)					
5	CH ₃	H	H	H	OCH ₃	H
	(N-[3-(4,5-dihydro-1H-imidazol-2-ylmethyl)-5-methoxy-phenyl]-methanesulfonamide)					
	CH ₃ CH ₂	H	H	H	H	CH ₃
	(ethanesulfonic acid[5-(4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methyl-phenyl]-amide)					
10	CH ₃	H	OCH ₃	H	H	H
	(N-[3-4,5-dihydro-1H-imidazol-2-ylmethyl)-2-methoxy-phenyl]-methanesulfonamide)					

Response to Arguments

Applicant's arguments filed November 29, 2006 have been considered. Applicant argues that the genus of the instant claimed compounds has been reduced to cover seven specific compounds since additional comparison data was not available. Applicant argues that the showing of the Rule 1.132 Declaration is now commensurate in scope with the currently amended claims. In response, the showing in the Declaration is insufficient for reasons stated above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48, 51, 52 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8, 10, 12-14, 18, 20, 27-30, 32, 44-47, 56-58, 60 and 64 of U.S. Patent No. 5,952,362 (Cournoyer et al.). Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the instant claimed compounds are positional isomers of the compounds claimed in U.S. Patent No. 5,952,362.

In U.S. Patent No. 5,952,362, see claim 1 (columns 124-125) and especially claim 27 (column 127) and claim 44 (column 128). The sulfonamide group in the compounds found in U.S. Patent No. 5,952,362 is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer). Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as claimed in U.S. Patent No. 5,952,362 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare positional isomers of the compounds claimed in

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U.S. Patent No. 5,952,362, to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating, for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed November 29, 2006 have been considered. Applicant argues that Declaration under 37 CFR 1.132 filed May 10, 2006 by Counde O-Yang demonstrates unexpected better ability of the claimed compounds to increase IUP without causing an undesirable increase in blood pressure compared to the compounds of Cournoyer et al. In response, the Declaration shows that one of the instant claimed compounds demonstrates unexpected better ability to increase IUP without causing an undesirable increase in blood pressure compared to the compounds of Cournoyer

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et al. However, the Declaration under 37 CFR 1.132 filed May 10, 2006 by Counde O-Yang was still considered insufficient for reasons stated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48, 51, 52 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Cournoyer et al. {U.S. Pat. 5,952,362} for reasons set forth below.

The applied reference has a common inventor (i.e., Counde O'Yang) with the instant application. Based

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upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35

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U.S.C. 103(c) as prior art in a rejection under 35

U.S.C. 103(a). See MPEP § 706.02(1)(1) and §

706.02(1)(2).

Claims 48, 51, 52 and 54 are rejected under 35
U.S.C. 103(a) as being unpatentable over Cournoyer et
al. {U.S. Pat. 5,952,362}.

*Determination of the scope and content of the prior art (MPEP
§2141.01)*

Applicant claims imidazolin-2-yl-methylphenyl
compounds. Cournoyer et al. teach imidazolin-2-yl-
methylphenyl compounds that are structurally similar to
the instant claimed compounds. See in Cournoyer et
al., for example, formula 1 in columns 7 and 8 and
especially the first compound listed in the table in
column 39.

*Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)*

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The difference between the compounds of Cournoyer et al. and the compounds instantly claimed is that the sulfonamide group is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer).

*Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)*

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Cournoyer et al., since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare positional isomers of the compounds taught by Cournoyer et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating,

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for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Response to Arguments

Applicant's arguments filed November 29, 2006 have been considered. Applicant argues that Declaration under 37 CFR 1.132 demonstrates unexpected better ability of the claimed compounds to increase IUP without causing an undesirable increase in blood pressure compared to the compounds of Cournoyer et al. In response, the Declaration shows that one of the instant claimed compounds demonstrates unexpected better ability to increase IUP without causing an undesirable increase in blood pressure compared to the compounds of Cournoyer et al. However, the Declaration under 37 CFR 1.132 filed May 10, 2006 by Counde O-Yang

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was still considered insufficient for reasons stated above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will

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be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 53 and 55-62 drawn to an invention nonelected without traverse in the reply filed December 16, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

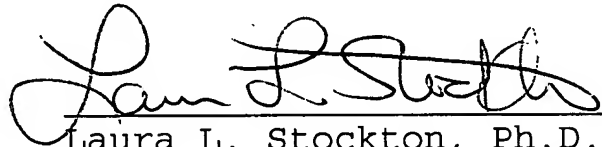
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information

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Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

February 5, 2007